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10/765,754	01/27/2004	Richard P. Rava	MAIT-006CX	1899

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EXAMINER	
SMITH, RUTH S	

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3737	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/765,754	RAVA ET AL.	
	Examiner	Art Unit	
	Ruth S. Smith	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 19-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 19-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Objections

Claims 4,27,28 are objected to because of the following informalities: It is unclear as to what further structural limitations have been set forth. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9,19-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,690,966 in view of Hessel et al(4,878,725) or Baker et al (5,042,980). The specific parameters set forth regarding the laser light are well known operating parameters in the diagnostic optical art. Hessel et al and Baker et al each disclose that it is known to provide a fiber optic catheter that delivers radiation in a radial direction in order to obtain information from a vessel in a patient. It would have been obvious to have modified the claimed invention such that the radiation is emitted and collected from a radial direction in order to obtain information from the vessel in which the catheter is positioned.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4,19-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kittrell et al in view of Muller alone or further in view of Hessel et al(4,878,725) or Baker et al (5,042,980). Kittrell et al disclose a spectroscopic diagnostic system and method for measuring tissue. The system includes a laser for emitting radiation and a fiber optic cable optically coupled to the laser to deliver the radiation to the tissue and detect radiation from the tissue. Kittrell et al disclose that any number of characteristics can provide spectroscopic signals useful in diagnosing tissue. Kittrell et al disclose that reflection, Raman scattering as well as fluorescence can be used to diagnose tissue. Kittrell et al also disclose the need to remove background light from the detected signal. Muller discloses a molecular spectroscopic diagnostic system and method for measuring tissue. Muller discloses using laser Raman spectroscopy to diagnose a body condition. Muller also discloses the use of infrared radiation in order to avoid the disturbance by fluorescence caused by high fluorescence background levels. It would have been obvious to one skilled in the art to have modified Kittrell et al such that it

performs reflection or Raman spectroscopy in view of the teachings of Kittrell et al that such is a known type of optical measurement of tissue and to have further modified Kittrell et al such that it operates in the infrared range to avoid to disturbance due to background fluorescence. Kittrell et al disclose that the light emanating from the optical fibers is in the form of a cone. Therefore, the light is considered to be delivered in a radial direction. In the event that applicant does not agree that the claims read on this limitation, Hessel et al(4,878,725) and Baker et al (5,042,980) each disclose an optical catheter including means for delivering radiation in a radial direction at a distal end of a fiber optic catheter and for collecting radiation returning radially from a body lumen. It would have been obvious to one skilled in the art to have further modified Kittrell et al such that the light is directed in a radial direction at a distal end of the catheter in order to obtain data from a greater surface area in the lumen of interest. Kittrell et al disclose that the laser catheter can have general applicability for in vivo medical use. Therefore, it would have been obvious to one skilled in the art to have used the device of Kittrell et al to diagnose the presence of any known type of tissue or medical condition.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kittrell et al in view of Muller or further in view of Hessel et al(4,878,725) or Baker et al (5,042,980) as applied to claim 1 above, and further in view of Wyatt. Wyatt discloses the use of an infrared laser light source to examine tissue where the output power of the source is within the range set forth in the claim. It would have been obvious to one skilled in the art to have further modified Kittrell et al such that the laser emits light within a range of 2 to 20 mW. Such a modification involves the selection of a known operating parameter in an optical system for examining tissue.

Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kittrell et al in view of Williamson et al alone or further in view of Hessel et al or Baker et al. Kittrell et al disclose a spectroscopic diagnostic system and method for measuring tissue. The system includes a laser for emitting radiation and a fiber optic cable optically coupled to the laser to deliver the radiation to the tissue and detect radiation from the

tissue. Kittrell et al disclose that any number of characteristics can provide spectroscopic signals useful in diagnosing tissue. Kittrell et al disclose that Raman scattering can be used to diagnose tissue. Kittrell et al also disclose the need to remove background light from the detected signal. It would have been obvious to one skilled in the art to have modified Kittrell et al such that it performs Raman spectroscopy in view of the teachings of Kittrell et al that such is a known type of optical measurement of tissue. The use of a spectroscope and CCD for detecting Raman spectra is old and well known as shown for example by Williamson et al. It would have been obvious to one skilled in the art to have further modified Kittrell et al such that the analyzer used comprises a spectrometer and a CCD detector. The modification merely involves the substitution of one well known type of detector and analyzer for another. The modified system would inherently be capable of detecting the light with the CCD for a period of 5 minutes or less. It is a well known expedient in the medical art to reduce the amount of time necessary to collect data used to provide a diagnosis. Therefore, one skilled in the art would have necessarily taken advantage of this inherent capability of the modified system. Kittrell et al disclose that the light emanating from the optical fibers is in the form of a cone. Therefore, the light is considered to be delivered in a radial direction. In the event that applicant does not agree that the claims read on this limitation, Hessel et al(4,878,725) and Baker et al (5,042,980) each disclose an optical catheter including means for delivering radiation in a radial direction at a distal end of a fiber optic catheter and for collecting radiation returning radially from a body lumen. It would have been obvious to one skilled in the art to have further modified Kittrell et al such that the light is directed in a radial direction at a distal end of the catheter in order to obtain data from a greater surface area in the lumen of interest.

Claims 1,4,6,7,9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al ('410) in view of Williamson et al and Hessel et al or Baker et al. Alfano et al disclose all of the claimed elements except for the use of a spectroscope and CCD and means for radially directing the light. The use of a spectroscope and CCD for detecting Raman spectra is old and well known as shown for example by Williamson et

al. It would have been obvious to one skilled in the art to modified Alfano et al such that the analyzer used comprises a spectrometer and a CCD detector. The modification merely involves the substitution of one well known type of detector and analyzer for another. The modified system would inherently be capable of detecting the light with the CCD for a period of 5 minutes or less. It is a well known expedient in the medical art to reduce the amount of time necessary to collect data used to provide a diagnosis. Therefore, one skilled in the art would have necessarily taken advantage of this inherent capability of the modified system. Hessel et al(4,878,725) and Baker et al (5,042,980) each disclose an optical catheter including means for delivering radiation in a radial direction at a distal end of a fiber optic catheter and for collecting radiation returning radially from a body lumen. It would have been obvious to one skilled in the art to have further modified Kittrell et al such that the light is directed in a radial direction at a distal end of the catheter in order to obtain data from a greater surface area in the lumen of interest.

Claims 2,3,8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al('410) in view of Williams et al and Hessel et al or Baker et al as applied to claims 1,7 above, and further in view of Kittrell et al. Kittrell et al disclose a spectroscopic diagnostic system and method for measuring tissue. The system includes a laser for emitting radiation and a fiber optic cable optically coupled to the laser to deliver the radiation to the tissue and detect radiation from the tissue. Kittrell et al disclose that any number of characteristics can provide spectroscopic signals useful in diagnosing tissue. Kittrell et al disclose that Raman scattering as well as fluorescence can be used to diagnose tissue. Kittrell et al also disclose the need to remove background light from the detected signal. It would have been obvious to one skilled in the art to have further modified Alfano et al such that the background components are removed from the detected light in order to provide a more accurate diagnosis.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al('410) in view of Williams et al and Hessel et al or Baker et al as applied to claim 1 above, and further in view of Wyatt. Wyatt discloses the use of an infrared laser light source to examine tissue where the output power of the source is within the range set forth in the claims. It would have been obvious to one skilled in the art to have further modified Alfano et al such that the laser emits light within a range of 2 to 20 mW. Such a modification involves the selection of a known operating parameter in an optical system for examining tissue.

Claims 19-26,28-30,32-36,38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al ('410) in view of Hessel et al or Baker et al. Alfano et al disclose a spectroscopic system and method for diagnosing the condition of tissue in a body lumen (figures 5,6). Alfano et al disclose the use of Raman spectroscopy operating in the infrared range. The system includes the use of an optical fiber bundle provided in a catheter (figures 5,6). Alfano et al fails to disclose the use of means for radially directing the light to the target. Hessel et al(4,878,725) and Baker et al (5,042,980) each disclose an optical catheter including means for delivering radiation in a radial direction at a distal end of a fiber optic catheter and for collecting radiation returning radially from a body lumen. It would have been obvious to one skilled in the art to have modified Alfano et al such that the light is directed in a radial direction at a distal end of the catheter in order to obtain data from a greater surface area in the lumen of interest. While Alfano et al disclose that the laser catheter can be used to determine the presence of cancer, it would have been obvious to one skilled in the art to have used the device of Alfano et al to diagnose the presence of any known type of tissue or medical condition.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al('410) in view of Hessel et al or Baker et al as applied to claim 30 above, and further in view of Kittrell et al. Kittrell et al disclose a spectroscopic diagnostic system and method for measuring tissue. The system includes a laser for emitting radiation and a

fiber optic cable optically coupled to the laser to deliver the radiation to the tissue and detect radiation from the tissue. Kittrell et al disclose that any number of characteristics can provide spectroscopic signals useful in diagnosing tissue. Kittrell et al disclose that Raman scattering as well as fluorescence can be used to diagnose tissue. Kittrell et al also disclose the need to remove background light from the detected signal. It would have been obvious to one skilled in the art to have further modified Alfano et al such that the background components are removed from the detected light in order to provide a more accurate diagnosis.

Response to Arguments

Applicant's arguments with respect to claims 1-9,19-38 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S. Smith whose telephone number is 571-272-4745. The examiner can normally be reached on M-F 7:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth S. Smith/
Primary Examiner, Art Unit 3737

RSS